UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ISABEL L. BECKER, as Administratix of the Estate of Deceased, NORWIN H. BECKER, and ISABEL L. BECKER, Individually, Plaintiffs, - against - CEPHALON, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	Case No. 7:14-cv-3864 (NSR)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

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INTRODUCTION[1]

Plaintiffs' Amended Complaint falls woefully short of stating a plausible claim. Although the gravamen of the Amended Complaint is that Defendant drug manufacturer Cephalon failed to warn physicians and patients of the possibility of developing Stevens Johnson Syndrome/Toxic Epidermal Necrolysis ("SJS/TEN") when taking Cephalon's anti-cancer drug TREANDA, the Amended Complaint fails to cite to or even mention the most important feature of any failure-to-warn claim: TREANDA's label. That label, which any physician would have access to as a medical professional and any patient would have access to through the drug's website, makes clear that Cephalon expressly warned both physicians and patients of the possibility of developing SJS/TEN when taking TREANDA. Feb. 2010 TREANDA Label, Ex. A.[2] Since TREANDA's label communicated information regarding the precise injury alleged, it is adequate as a matter of law, and Plaintiffs' failure-to-warn claim fails as a result.

Plaintiffs' other claims fail as well. First, Plaintiffs' warranty claim fails both because Plaintiffs failed to provide pre-litigation notice to Cephalon and because Plaintiffs failed to plead reliance. Second, Plaintiffs' false advertising claim fails both because such claims are barred by New York's Informed Intermediary Doctrine and because Plaintiffs failed to plead reliance. Finally, Plaintiffs' misrepresentation claim fails because Plaintiffs do not allege the privity

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[1] Unless otherwise noted, all internal citations and quotations are omitted and all emphasis has been added.

[2] All citations in the form of "Ex. ___" refer to exhibits to the Declaration of Devora W. Allon in Support of Defendants' Motion to Dismiss, filed contemporaneously herewith. On a motion to dismiss, courts may take judicial notice of the content of a document, like the TREANDA label attached hereto, when it is a "public record," *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 610 (S.D.N.Y. 2012), and is "integral to the complaint," *Mangiafico v. Blumenthal*, 471 F.3d 391, 398 (2d Cir. 2006). Courts have recognized that they can take judicial notice of drug labels in particular "because the label can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." *Chapman v. Abbott Labs.*, 930 F. Supp. 2d 1321, 1323 (M.D. Fla. 2013).

The full TREANDA label in effect at the time Mr. Becker was administered TREANDA is available on the Food and Drug Administration website and is attached. *See* Ex. A, Feb. 2010 TREANDA label, *available at* www.accessdata.fda.gov/drugsatfda_docs/label/2010/022249s005lbl.pdf.

necessary to establish a negligent misrepresentation claim. For these reasons, and the reasons detailed below, Plaintiffs' Amended Complaint should be dismissed in its entirety, with prejudice.

BACKGROUND

The Amended Complaint alleges that Norwin H. Becker was injured "as a result of his and his physician's reliance on intentional misrepresentations" by Cephalon.[3] (Am. Compl. ¶ 1.) Plaintiffs allege that Cephalon provided information "that was misleading and suggestive of the absence of . . . risks" for its drug TREANDA. (Am. Compl. ¶ 1.) As a result, Plaintiffs claim that Mr. Becker suffered from a "toxic skin reaction resulting horrendous and repeating exfoliative dermatitis such as or similar to [SJS/TEN]." (Am. Compl. ¶ 1.) The Amended Complaint contains no allegation either that (1) Mr. Becker was ever diagnosed with SJS/TEN or (2) that any medical professional determined that TREANDA caused Mr. Becker's alleged SJS/TEN.

According to the Amended Complaint, Mr. Becker was administered allopurinol in connection with his cancer treatment on or about December 8, 2010. (Am. Compl. ¶ 8.) The Amended Complaint also alleges that Mr. Becker was administered TREANDA in connection with his cancer treatment on or about December 14, 2010, December 15, 2010, December 20, 2010, January 10, 2011, January 19, 2011, and January 26, 2011. (Am. Compl. ¶ 9.)

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[3] Although Plaintiffs' allegations focus exclusively on Cephalon's conduct, Plaintiffs also name Teva Pharmaceuticals, Inc. ("Teva") as a defendant. However, Plaintiffs' allegations against Teva should be dismissed because as noted in the Amended Complaint, Teva "is a company organized and headquartered in Israel." (Am. Compl. ¶ 6.) Thus, this Court lacks personal jurisdiction over Teva. *See, e.g., Krepps v. Reiner*, 414 F. Supp. 2d 403, 411 (S.D.N.Y. 2006) (dismissing action for lack of personal jurisdiction where plaintiff failed to established that defendant "ha[d] a corporate presence" in New York); *J.L.B. Equities, Inc. v. Ocwen Fin. Corp.*, 131 F. Supp. 2d 544, 553 (S.D.N.Y. 2001) (dismissing complaint for lack of personal jurisdiction where defendant was located in a state other than New York).

On March 30, 2009, well before Mr. Becker's physician even considered prescribing TREANDA to Mr. Becker and more than a year before the Amended Complaint alleges Mr. Becker was actually administered TREANDA, Cephalon submitted a supplemental new drug application to the FDA, which proposed revising TREANDA's package insert "to include reports of adverse events of [SJS/TEN]." (Apr. 22, 2009 Letter, Ex. B, at 1.) After review of the proposed label, the FDA approved Cephalon's application "for use as recommended in the agreed-upon labeling text." (*Id.*)

The FDA-approved TREANDA label in effect when Mr. Becker was administered TREANDA included the following warnings on the potential risk of SJS/TEN:[4]

> **WARNINGS AND PRECAUTIONS**
>
> Skin Reactions: Discontinue for severe skin reactions. ***Cases of SJS and TEN, some fatal, have been reported when TREANDA was administered concomitantly with allopurinol and other medications known to cause these syndromes.***
>
> * * *
>
> **WARNINGS AND PRECAUTIONS**
>
> **5.5 Skin Reactions**
>
> ***A number of skin reactions have been reported in clinical trials and post-marketing safety reports.*** These events have included rash, toxic skin reactions and bullous exanthema. Some events occurred when TREANDA was given in combination with other anticancer agents, so the precise relationship to TREANDA is uncertain.
>
> In a study of TREANDA (90 mg/m2) in combination with rituximab, one case of toxic epidermal necrolysis (TEN) occurred. TEN has been reported for rituximab (see rituximab package insert). ***Cases of Stevens-Johnson syndrome (SJS) and TEN, some fatal, have been reported when TREANDA was administered***

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[4] The FDA approved a revised TREANDA label on December 21, 2010. *See* Ex. C, Dec. 2010 TREANDA label, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022249s006lbl.pdf. This label, however, only added "phlebitis" as a possible side effect and did not impact the warning regarding SJS/TEN. *See id.*

concomitantly with allopurinol and other medications known to cause these syndromes. The relationship to TREANDA cannot be determined.

Where skin reactions occur, they may be progressive and increase in severity with further treatment. Therefore, patients with skin reactions should be monitored closely. ***If skin reactions are severe or progressive, TREANDA should be withheld or discontinued.***

* * *

6 ADVERSE REACTIONS

6.3 Post-Marketing Experience

The following adverse reactions have been identified during post-approval use of TREANDA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: anaphylaxis; and injection or infusion site reactions including pruritus, irritation, pain, and swelling.

Skin reactions including SJS and TEN have occurred when TREANDA was administered concomitantly with allopurinol and other medications known to cause these syndromes.

(Feb. 2010 TREANDA Label, Ex. A, at 1, 3, 4.)

LEGAL STANDARD

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a complaint must "state[] a plausible claim for relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). A claim is "plausible" only where it contains "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678. On a motion to dismiss, a court should not accept either "a legal conclusion couched as a factual allegation" or, like the Amended Complaint here, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Id.* A complaint "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation" and must be dismissed where the allegations show only "the mere possibility of misconduct." *Id.* at 678-79.

ARGUMENT

I. PLAINTIFFS' STRICT LIABILITY AND NEGLIGENCE CLAIMS FAIL BECAUSE CEPHALON'S WARNINGS WERE ADEQUATE AS A MATTER OF LAW.

Plaintiffs' strict liability and negligence claims both fail because Cephalon adequately warned Mr. Becker's physician of the risk of SJS/TEN.[5] To recover for an injurious side effect from a properly manufactured prescription drug, a plaintiff must prove "that the drug caused her injury and that the manufacturer breached a duty to warn of the possibility that the injurious reaction might occur." *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 90-91 (2d Cir. 1980). This "duty to warn" extends to "all potential dangers which it knew, or in the exercise of reasonable care should have known, to exist." *Id.*

As the New York Court of Appeals explained in *Martin v. Hacker*, "[a] warning for a prescription drug may be held adequate as a matter of law." 83 N.Y.2d 1, 10 (1993). A prescription drug warning is adequate when "information regarding the precise malady incurred was communicated in the prescribing information." *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009) (finding warning adequate where label warned of symptoms allegedly suffered by plaintiff); *Fane v. Zimmer, Inc.*, 927 F.2d 124, 130 (2d Cir. 1991) (finding warnings adequate as a matter of law where they "provided specific information on the risks"); *Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 61-62 (4th Dep't 1979), *aff'd*, 52 N.Y.2d 768 (1980) ("[W]here the warning given to the prescribing physician by the manufacturer through the Physician's Desk Reference [PDR], package inserts and other literature gives specific detailed information on the risks of the drug, the manufacturer has been absolved from liability as a

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[5] In New York, "failure to warn claims are identical under strict liability and negligence theories of recovery." *DiBartolo*, 914 F. Supp. 2d at 611.

matter of law.").[6] Because Cepahlon included in TREANDA's label an express, specific, and detailed warning that informed Mr. Becker's physician not just of the relevant risks, but also of the specific risk that Plaintiffs now allege Mr. Becker did not know–that TREANDA administered concomitantly with allopurinol could cause SJS/TEN–TREANDA's label was adequate as a matter of law and Plaintiffs' failure-to-warn and negligence claims both fail.

A. TREANDA's Label Expressly Warned of SJS/TEN.

It strains credulity for Plaintiffs to allege that "Cephalon breached its duty to provide physicians with adequate and timely notice" of the risk of SJS/TEN, Am. Compl. ¶ 12, because physicians were provided with adequate and timely notice of the correlation between TREANDA and SJS/TEN. TREANDA's "FDA-approved warning label[] warn[s] of the very injuries plaintiff[] ha[s] pled." *Reed*, 839 F. Supp. 2d at 575 (granting motion to dismiss on failure-to-warn claim where plaintiff could not show warning label was inadequate). Critically, TREANDA's label described how "[c]ases of [SJS/TEN] . . . have been reported when TREANDA was administered concomitantly with allopurinol and other medicals known to cause these syndrome." (Feb. 2010 TREANDA Label, Ex. A at 3, 4.) And the label did not stop there. It went on to warn that skin reactions could be "progressive and increase in severity" and thus "[i]f skin reactions are severe or progressive, TREANDA should be withheld or discontinued." *Id.* In another section of the label, Cephalon repeated the warning: "Skin reactions including SJS and TEN have occurred when TREANDA was administered concomitantly with allopurinol and

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[6] Courts in other jurisdictions have also addressed failure-to-warn claims as a matter of law. *Ferrara v. Berlex Labs., Inc.*, 732 F. Supp. 552, 555 (E.D. Pa.), *aff'd*, 914 F.2d 242 (3d Cir. 1990) ("We concur with the defendants' argument that the learned intermediary doctrine precludes strict liability from being imposed on the drug manufacturers."); *Williams v. Ciba-Geigy Corp.*, 686 F. Supp. 573, 575 (W.D. La.), *aff'd sub nom. Williams v. Ciba Geigy*, 864 F.2d 789 (5th Cir. 1988) ("This court holds that . . . as a matter of law, the drug [] is not unreasonably dangerous per se . . . ."); *Brick v. Barnes-Hines Pharm. Co.*, 428 F. Supp. 496, 497 (D.D.C. 1977) (granting summary judgment on "pure question of law"). Further, failure-to-warn cases have been dismissed at the motion to dismiss stage. *See, e.g., Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 573 (E.D.N.Y. 2012) (dismissing failure-to-warn claim with prejudice).

other medications known to cause these syndromes." *Id.* These detailed and informative warnings dispose of a failure-to-warn claim. *See Alston*, 670 F. Supp. 2d at 284 (finding warning adequate where label warned of symptoms allegedly suffered by plaintiff).

This Court recently found a similar warning label to be adequate as a matter of law. In *McDowell v. Eli Lilly and Co.*, the plaintiff alleged that the "anti-depression drug Cymbalta failed to warn adequately about the risk of withdrawal upon continuance . . . ." No. 13 Civ. 3786, 2014 WL 5801604, at *1 (S.D.N.Y. Nov. 6, 2014). After examining the drug's label, this Court granted the defendant's summary judgment motion as a matter of law, finding that the drug's label included "a recitation of the specific symptoms possible upon Cymbalta discontinuation (including the symptoms alleged by the Plaintiff) . . . ." *Id.* at *11. Therefore, this Court concluded that the Cymbalta label was "adequate as a matter of law because it [was] accurate, clear, consistent on its face and portray[ed] with sufficient intensity the risk involved in taking the drug." *Id.* at *15.

The same is true here. At the time Mr. Becker was administered TREANDA, the label "plainly and prominently identified" the risk of SJS/TEN–the disease Mr. Becker allegedly suffered from. *See In re Accutane Prods. Liab.*, MDL No. 1626, 2012 WL 3194954, at *5 (M.D. Fla. July 24, 2012) (applying New York law and finding label adequate where it directly warned of IBD, the side effect allegedly suffered by the plaintiff). TREANDA's label "also identified the common symptoms" of SJS/TEN and "instructed what should be done if those symptoms appeared." *Id.* TREANDA's label was "accurate, clear, [and] consistent on its face" and it "portray[ed] with sufficient intensity the risk involved in taking the drug." *McDowell*, 2014 WL 5801604, at *15.

B. TREANDA's Website and Dosing Card Are Not Relevant to the Failure-to-Warn Claim or Negligence Claims.

Rather than addressing TREANDA's label–which as discussed above is fatal to Plaintiffs' failure-to-warn and negligence claims–the Amended Complaint instead cites to other sources of drug information that it claims deprived Mr. Becker's physician of "the opportunity to consider that TREANDA . . . [was] not reasonably safe."[7] (Am. Compl. ¶ 17.) In particular, the Amended Complaint focuses on TREANDA's dosing card, Am. Compl. ¶ 12, and website, Am. Compl. ¶¶ 14, 15. As an initial matter, Plaintiffs' claims rest on the legally flawed assumption that Mr. Becker's physician would have considered such materials and ignored the clear warning discussed above. *See In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 813 (N.D. Ohio 2004), *aff'd sub. nom. Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861 (6th Cir. 2006) ("Defendants conveyed the warning on a product insert-something that one may reasonably assume that physicians will read."). But even if TREANDA's label had not been adequate as a matter of law, TREANDA's dosing card and website are still irrelevant to a failure-to-warn analysis.

Although the Amended Complaint repeatedly refers to TREANDA's dosing card, the only language actually cited in the Amended Complaint is from a letter from the FDA to Cephalon. Findings by the FDA are irrelevant to this case because the standard employed by the FDA is different than the standard in a New York court on a failure-to-warn claim. *See, e.g., DiBartolo*, 914 F. Supp. 2d at 627 (noting how FDA standards are different than legal standards in New York). Moreover, past marketing violations have "no discernable relevance" to Plaintiffs' claims. *King v. Pfizer Pharm. Co.*, No. RWT 11CV00127, 2011 WL 3157305, at *3

[7] As discussed below *supra* Section IV, although the Amended Complaint alleges that these materials were misleading to Mr. Becker's physician, it does not allege that Mr. Becker's physician ever saw these materials or considered them.

(D. Md. July 25, 2011) (granting motion to dismiss on failure-to-warn claim where plaintiff could not show how drug manufacturer's past improper practices affected her physician's ability to understand the drug's risks). The FDA letter also proves too much. First, the letter makes clear that Cephalon directly warned of SJS/TEN on TREANDA's label. (December 18, 2009 FDA Letter, Ex. E, at 2.) Moreover, as evidenced by the letter itself, the FDA never specifically disciplined or warned Cephalon for publishing anything misleading regarding TREANDA's association with SJS/TEN. *Id.*

The Amended Complaints' allegations with respect to TREANDA's website are even more puzzling. On the one hand, Plaintiffs concede that TREANDA's website in February 2010 and June 2011 contained explicit warnings regarding the association between SJS/TEN and TREANDA. (Am. Compl. ¶¶ 14, 20, 22.) Curiously though, the Amended Complaint claims that the website did not contain that same information in December 2010, which is allegedly when Mr. Becker's physician would have been considering whether to administer TREANDA, though the Amended Complaint neither quotes from nor attaches that version. (Am. Compl. ¶ 15.) As such, the Amended Complaint's allegation regarding the website in December 2010 is conclusory and thus "not entitled to be assumed true." *Iqbal*, 556 U.S. at 664. Either way, the allegation is unavailing because failure-to-warn claims based on "marketing in the public domain," such as a website, are not cognizable. *See DiBartolo*, 914 F. Supp. 2d at 613-16. Thus, any failure-to-warn claim based on TREANDA's website fails because this Court must evaluate the label provided Mr. Becker's physician and not Cephalon's mass marketing.

II. PLAINTIFFS' OTHER CLAIMS FAIL BECAUSE THEY ARE GROUNDED IN A FAILURE-TO-WARN THEORY.

In addition to Plaintiffs' strict liability and negligence claims, the Amended Complaint also asserts claims for breach of warranty, Am. Compl. ¶ 31, false advertising, Am. Compl. ¶ 32,

and misrepresentation, Am. Compl. ¶ 33. These claims fail as well. Because Cephalon's warning to Mr. Becker's physician was adequate as a matter of law, all of Plaintiffs' other claims are barred. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, Civ. Action No. 12-1492, 2014 WL 2738224, at *12 (D.N.J. June 17, 2014) ("under New York law, the adequacy of the . . . warning label, as a matter of law, precludes any related claims for negligence, strict liability, breach of warranties, or fraud."). This Court recently reaffirmed this principle in *McDowell v. Eli Lilly & Co.*, dismissing claims for defective design, negligence, breach of implied warranty, negligent misrepresentation, fraud, and violation of consumer fraud claims because it found the label at issue to be adequate as a matter of law. 2014 WL 5801604, at *18. This is because "[r]elating a warning theory in terms of 'warranty' or 'fraud' does not avoid the implications of an adequate warning." *Id.* at *19.[8] Since all of Plaintiffs' other claims are grounded in a failure-to-warn theory, they should all be dismissed because TREANDA's label is adequate as a matter of law.

III. PLAINTIFFS' FAILURE-TO-WARN CLAIMS FAIL TO THE EXTENT THEY ARISE OUT OF A DUTY TO WARN THE GENERAL PUBLIC.

The Amended Complaint asks this Court to accept a theory that has been repeatedly rejected by this Court and other courts throughout the State–that drug manufacturers owe a duty to warn the general public of all drug risks. The Amended Complaint alleges that Cephalon "had a duty to not mislead ***prospective patients***, including decedent, with targeted publication of affirmative misstatements that would lead patients to believe that treatment with TREANDA

[8] Courts in other jurisdictions have reached the same conclusion. *See, e.g.*, *In re Accutane*, 2012 WL 3194954, at *6 (holding that "under New York law, the adequacy of the warnings, as a matter of law, precludes any related claims for negligence, strict liability, breach of warranties, or fraud."); *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 709 (E.D. Tex. 1997) (granting summary judgment on all claims where "[t]he gravamen of all of Plaintiffs' causes of action . . . is that Wyeth failed to adequately warn of or disclose the severity of Norplant's side effects"), *aff'd* 165 F.3d 374 (5th Cir. 1999); *Jack v. Glaxo Wellcome Inc.*, 239 F. Supp. 2d 1308, 1320-22 (N.D. Ga. 2002) (finding that the learned intermediary doctrine precluded claims for negligence, strict liability, and breach of implied warranty).

does not incur serious risks." (Am. Compl. ¶ 18.) Even assuming that such "targeted publication of affirmative misstatements" occurred–which it did not–Plaintiffs' claims based on a supposed duty of a drug manufacturer to warn the general public are barred as a matter of law.

In order to properly plead a failure-to-warn claim, a plaintiff must show: (1) that a manufacturer has a duty to warn; (2) against dangers resulting from foreseeable uses about which it knew or should have known; and (3) that failure to do so was the proximate cause of harm. *Lewis v. Abbot Labs.*, No. 08 Civ. 7580 (SCR) (GAY), 2009 WL 2231701, at *5 (S.D.N.Y. July 24, 2009). New York applies the Informed Intermediary Doctrine which stands for the proposition that prescription drug warnings are intended for the physician and not the patient. *Martin*, 83 N.Y.2d at 9. As the New York Court of Appeals has explained:

> Warnings for prescription drugs are ***intended for the physician***, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects. The physician acts as an 'informed intermediary' between the manufacturer and the patient; and, ***thus, the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient.***

Id.; *Eli Lilly*, 2014 WL 5801604, at *10 ("Under New York law, a manufacturer's duty to warn of the risks of a prescription medicine runs to the prescribing medical professional, not an individual patient"); *DiBartolo*, 914 F. Supp. 2d at 611 (same); *Prohaska v. Sofamor, S.N.C.*, 138 F. Supp. 2d 422, 444 (W.D.N.Y. 2001) (same); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 259 (E.D.N.Y. 1999) (same); *Golod v. Hoffman La Roche*, 964 F. Supp. 841, 853 (S.D.N.Y. 1997) (same). A significant portion of the Amended Complaint is dedicated to allegations that Cephalon did not adequately warn Mr. Becker of TREANDA's risks, Am. Compl. ¶¶ 18-28, but these claims have no basis under New York law. *See, Lewis*, 2009 WL 2231701, at *5 (holding that plaintiff failed to allege "sufficient evidence to support a failure to warn claim" where plaintiff did not allege that the manufacturer "failed to provide warnings to her doctors").

IV. PLAINTIFFS' FAILURE-TO-WARN CLAIMS FAIL BECAUSE PLAINTIFFS DO NOT SUFFICIENTLY PLEAD CAUSATION AS A MATTER OF LAW.

The *sine qua non* of a failure-to-warn claim is proximate cause. And in order to show proximate cause, "a plaintiff must demonstrate that had a different, more accurate [warning] been given, his physician would not have prescribed the drug in the same manner." *Alston*, 670 F. Supp. 2d at 285 (finding that physician prescribed the drugs fully aware of the risks and thus plaintiff could not show proximate cause). The inadequate warning must be a "substantial cause for the events leading to the injury." *Erony v. Alza Corp.*, 913 F. Supp. 195, 200 (S.D.N.Y. 1995). But, accepting Plaintiffs' allegations as true, Plaintiffs fail to adequately plead proximate cause because the Amended Complaint is devoid of any such allegations. Instead, Plaintiffs claim, in conclusory fashion, that "[h]ad Cephalon properly instructed Dr. Lonberg, he would have advised decedent of [TREANDA's] risks." (Am. Compl. ¶ 17.) These allegations fail first because Cephalon provided an adequate warning as a matter of law and second because they do not meet the plausibility standard required on a motion to dismiss.

Cephalon's adequate warning dispels any notion that Mr. Becker's physician would have chosen a different course of treatment had the warning been different as a matter of law. As discussed in Section I, TREANDA contained an express warning that SJS/TEN could occur when TREANDA was administered concomitantly with allopurinol. Access to such a warning "demonstrates that a more stringent warning would have had no practical effect on the [physician's] actions." *See Alston*, 670 F. Supp. 2d at 285 (finding that plaintiff failed to show proximate cause because physician was aware that the drug could cause the symptom and thus a clearer warning would not have made a difference). Indeed, the Amended Complaint's only allegation regarding materials directed to Mr. Becker's physician concedes that there was an

express warning of SJS/TEN. (Am. Compl. ¶ 22 (". . . Cephalon's webpage addressed to Healthcare Professionals" disclosed side effects "including SJS/TEN.").)[9]

The Amended Complaint attempts to resurrect its claims by claiming that Mr. Becker's physician could have been deceived by Cephalon because of TREANDA's dosing card, Am. Compl. ¶ 12, internet search advertisements, Am. Compl. ¶ 13, and website, Am. Compl. ¶ 15. Even assuming that these sources of information were in some way misleading–which they were not–the Amended Complaint never alleges that Mr. Becker's physician considered or even saw these sources of information when making his decision to prescribe TREANDA to Mr. Becker. Thus, the allegation in the Amended Complaint fails to support the reasonable inference that Mr. Becker's physician would have chosen a different treatment had the warnings on those sources been different.

The vagueness of the Amended Complaint's allegations that Mr. Becker's physician would have chosen a different course of treatment had the warning been different highlight the implausibility of Plaintiffs' claim. The Amended Complaint alleges the following–which, even accepted as true, are all insufficient to survive a motion to dismiss:

- "Had the physician been afforded timely knowledge of the foreseeable risks of TREANDA, particularly with allopurinol, ***presumably he would have advised*** decedent of those risks" (Am. Compl. ¶ 1);
- "Cephalon Misled Physicians, ***Possibly*** Including Decedent's Physician, Dr. Lonberg" (Am. Compl. ¶¶ 9-10);
- ". . . Dr. Lonberg ***may have been misled***" (Am. Compl. ¶ 16);

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[9] The Amended Complaint's allegation that Mr. Becker's physician "manifested ignorance of severe skin reactions" further supports the notion that a different warning would not have altered his actions. (Am. Compl. ¶ 16.) Fully aware of the risk of SJS/TEN, since it was on TREANDA's label, Mr. Becker's physician still did not convey to Mr. Becker that there was a risk. While this failure to convey the risk to Mr. Becker may give rise to a medical malpractice claim against Mr. Becker's physician, it defeats a failure-to-warn claim. *See DiBartolo*, 914 F. Supp. 2d at 616.

- ". . . knowing of such foreseeable risks, [Dr. Lonberg] ***might not have prescribed*** TREANDA" (Am. Compl. ¶ 17); and

- "Had Cephalon properly instructed Dr. Lonberg, he would have advised decedent of the risks, and ***possibly declined*** to prescribe TREANDA" (Am. Compl. ¶ 17).

Such allegations fly in the face of what a plaintiff is required to plead on a motion to dismiss. As the Supreme Court has articulated:

> The plausibility standard is not akin to a probability requirement, but it asks for ***more than a sheer possibility*** that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, ***it stops short of the line between possibility and plausibility*** of entitlement to relief.

Iqbal, 556 U.S. at 678. Here, the Amended Complaint does not even allege enough facts to make its claim possible, let alone plausible. Therefore, even accepting Plaintiffs' allegations as true, Plaintiffs fail to state a plausible claim because they do not adequately plead proximate cause.

V. PLAINTIFFS' OTHER CAUSES OF ACTION FAIL FOR CLAIM SPECIFIC REASONS.

A. Plaintiffs' Warranty Claim Fails.

Even assuming Plaintiffs' warranty claim is more than just "tag along" claims and thus cognizable (*see* Section II), it fails for two independent reasons.

1. Plaintiffs Failed to Provide Pre-Litigation Notice.

New York law is indisputable: a "buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." N.Y. U.C.C. § 2-607(3)(a). Yet the Amended Complaint is conspicuously devoid of any allegation that Plaintiffs notified Cephalon that there was an alleged breach. This is true even though Plaintiffs allegedly accessed TREANDA's website over three years ago. (Am. Compl. ¶ 21.) Because of this failure to provide any pre-litigation notice, let alone notice within a reasonable time after discovery of breach, Plaintiffs' express warranty claim fails. *See In re*

Frito-Lay N. Am., Inc. All Natural Litig., No. 12-MD-2413, 2013 WL 4647512, at *27 (E.D.N.Y. Aug. 29, 2013) (dismissing plaintiffs' New York breach of warranty claim because plaintiffs "fail[ed] to allege in the [complaint] that they even provided sufficient notice to defendants of their express warranty claims . . . let alone notice within a reasonable time after discovery of a breach").

2. Plaintiffs Fail to Allege Reliance.

Even if this Court ignores Plaintiffs' failure to provide Cephalon with pre-litigation notice–which it should not–Plaintiffs' express warranty claim should be dismissed for the independent reason that the Amended Complaint fails to adequately allege reliance. To state a breach of express warranty claim, a plaintiff must allege "an affirmation of fact or promise by the seller, the natural tendency of which was to induce the buyer to purchase and that the warranty was relied upon to the Plaintiffs' detriment." *DiBartolo*, 914 F. Supp. 2d at 625. Here, Plaintiffs cannot demonstrate that Mr. Becker or his physician relied on any affirmation of fact or promise.

As discussed previously in Section IV, Plaintiffs do not allege any facts to support a finding that Mr. Becker's physician relied on any specific misrepresentation when choosing to prescribe TREANDA. The same is true for Mr. Becker. Although the Amended Complaint alleges that Mr. Becker "relied" on a "misleading statement" in December 2010 which "was materially identical" to the website accessed in 2011, the Amended Complaint does not cite to any specific advertisement. (Am. Compl. ¶ 21). Instead, it simply quotes portions of TREANDA's website accessed after Mr. Becker died. (Am. Compl. ¶¶ 13, 14.) It is impossible to show Mr. Becker's reliance on a specific website when the Amended Complaint itself concedes that Plaintiffs only accessed it after the date of Mr. Becker's death. The Amended

Complaint fails to cite a single printout or excerpt from a website that Mr. Becker could have feasibly relied on. Without reliance, Plaintiffs' express warranty claim fails.

3. Plaintiffs' Breach of Implied Warranty Claim Fails.

Any claim based on an implied warranty fails as well.[10] To state a claim for breach of the implied warranty of merchantability, a plaintiff must show that "a defect in the product was a substantial factor in causing the injury and . . . that the defect complained of existed at the time the product left the manufacturer or entity in the line of distribution being sued." *DiBartolo*, 914 F. Supp. 2d at 627. Plaintiffs cannot allege an implied warranty claim because TREANDA's label was adequate as a matter of law. (*See* Section I). Thus, Plaintiffs cannot show that the product's "defect," which would be the failure to warn, was a substantial factor in causing the injury.

B. Plaintiffs' False Advertising Claim Fails.

Plaintiffs' false advertising claim, presumably based on N.Y. Gen. Bus. Law § 350 also fails because (1) claims under the General Business Law are not cognizable under New York's Informed Intermediary Doctrine and (2) Plaintiffs fails to allege that Mr. Becker or his physician ever saw the allegedly misleading advertisement.

First, Plaintiffs' false advertising claim fails because it is inherently inconsistent with New York's Informed Intermediary Doctrine, as discussed in Section II. Although New York courts have not yet directly confronted this issue, courts from other jurisdictions have acknowledged that the doctrine "precludes Plaintiffs' claim under the consumer protection statute." *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 552 (E.D. Pa. 2006), *aff'd*, 521 F.3d 253 (3d Cir. 2008) *cert. granted, judgment vacated on other grounds*, 556 U.S. 1101 (2009).

[10] It is unclear whether Plaintiffs' Amended Complaint asserts a breach of express or implied warranty, so both are addressed.

The District of New Jersey reached the same conclusion when examining Pennsylvania's consumer protection statute. Specifically, in *Heindel v. Pfzier, Inc.*, the court noted that the plaintiffs could not sustain an action under the consumer protection statute because the informed intermediary doctrine did not require manufacturers to warn consumers. 381 F. Supp. 2d 364, 384 (D.N.J. 2004).

Second, Plaintiffs' false advertising claim fails because although the Amended Complaint makes vague allegations that Mr. Becker "relied" on specific advertisements, noticeably absent is a single allegation that Mr. Becker actually saw any of the alleged representations. (*See* Section V.) This glaring deficiency in the Amended Complaint dooms Plaintiffs' false advertising claim. *See In re Fosamax*, 2013 WL 1558697, at *8 (applying New York law and rejecting General Business Law false advertising claim where the plaintiff had not seen the advertisements).

C. Plaintiffs' Misrepresentation Claim Fails.

Lastly, Plaintiffs' misrepresentation claim also fails because the Amended Complaint fails to allege privity, a necessary requirement of a negligent misrepresentation claim.[11] As this Court explained in *Jurgensen v. Felix Storch, Inc.*, the "*sine qua non* of a negligent misrepresentation claim is that the defendant had a duty—as a result of a special or privity-like relationship—to provide correct information to the plaintiff." No. 12 CIV 1201 (KBF), 2012 WL 2354247, at *9 (S.D.N.Y. June 14, 2012). Where there is no privity of contract, a plaintiff must show: "(1) an awareness by the maker of the statement that it is to be used for particular purpose; (2) reliance by a known party on the statement in furtherance of that purpose; and (3)

[11] It is unclear whether Plaintiffs' misrepresentation claim is grounded in strict liability misrepresentation or negligent misrepresentation. Because New York has not adopted the strict liability approach to misrepresentation, *DiBartolo*, 914 F. Supp. 2d at 623, only negligent misrepresentation is addressed.

some conduct by the maker of the statement linking it to the relying party and evincing its understanding of that reliance." *DiBartolo*, 914 F. Supp. 2d at 623-24.

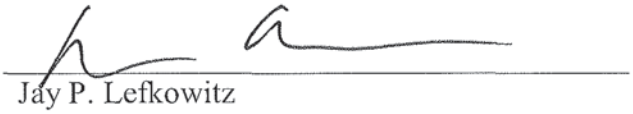
The Amended Complaint fails to meet either of these standards. Mr. Becker was not in privity of contract with Cephalon, and the Amended Complaint does not allege that Mr. Becker was a known party to Cephalon or that Cephalon "undertook specific conduct linking it to [him] and evincing its understanding of [his] alleged reliance on its ads." *Id.* at 624 (dismissing negligent misrepresentation claim). Without privity, Plaintiffs' negligent misrepresentation claim fails as a matter of law. *See, e.g., Naughright v. Weiss*, 826 F. Supp. 2d 676, 688 (S.D.N.Y. 2011) ("To allege a special relationship, [the plaintiff] must establish something beyond an ordinary arm's length transaction . . . ."); *DiBartolo*, 914 F. Supp. 2d at 624 ("[A]lthough Plaintiffs' amended complaint includes numerous allegations that [the company's] advertising was misleading . . . plaintiff cannot satisfy the elements of a claim for negligent misrepresention" because "[p]laintiff was not in privity of contract."); *Jurgensen*, 2012 WL 2354247, at *9 (dismissing claim because defendant's sale of a freezer to plaintiff did not reach the requisite level of privity).

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Amended Complaint be dismissed with prejudice.

Dated: New York, New York
December 15, 2014

Kirkland & Ellis LLP



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